4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0674]

Draft Guidance for Industry: Food and Drug Administration Records Access Authority Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act." This draft guidance provides updated information pertaining to FDA's authority to access and copy records relating to food. It is a revision of FDA's November 2005 guidance entitled "Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Guidance."

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Outreach and Information Center (HFS-009), Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one

self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act." The draft guidance is intended for persons who manufacture, process, pack, hold, or import human or animal foods intended for distribution to consumers, institutions, or food processors. This draft guidance provides updated information pertaining to FDA's authority to access and copy records relating to food under sections 414(a) and 704(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350c(a) and 21 U.S.C. 374(a)(1)(B),

respectively), as amended by section 101 of the FDA Food Safety and Modernization Act (FSMA) (Public Law 111-353) of January 4, 2011.

Section 414 was originally added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). FSMA, signed into law on January 4, 2011, expanded FDA's access to records under section 414. Prior to the passage of FSMA, section 414(a) of the FD&C Act provided the Secretary (by delegation FDA) with authority to access records relating to food that was reasonably believed to be adulterated and to present a threat of serious adverse health consequences or death to humans or animals. Now under section 414(a)(1), as amended by FSMA, FDA's records access extends beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, under section 414(a)(2), FDA can access records if it believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Furthermore, FSMA revised section 704(a)(1)(B), which pertains to factory inspections, to refer to the amended version of section 414(a).

This updated draft guidance is intended to provide individuals in the human and animal food industries with an overview of FDA's authority to access and copy records. It provides practical information by answering common questions that cover a range of topics, including when FDA has the authority to access and copy records, the circumstances under which FDA is likely to request records, the types of records FDA may request and copy, and the consequences of refusing to provide records access. The Agency has adopted good guidance practices (GGPs) that set forth the Agency's policies and procedures for the development, issuance, and use of

guidance documents (21 CFR 10.115). This draft guidance is being issued as level 1 guidance consistent with GGPs.

The draft guidance, when finalized, will represent the Agency's current thinking on its authority to access and copy records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in

brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Always access an FDA guidance document by using the Web sites listed previously to find the most current version of the guidance.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4166 Filed 02/22/2012 at 8:45 am; Publication Date: 02/23/2012]